II. REMARKS

Preliminary Remarks:

The specification is amended to update references to related U.S. applications and to correct informalities.

Claims 42, 48, and 49 are amended, new claims 71-73 are added, and claims 60-70 are canceled as being redundant.

Claim 42 is amended to be directed to a chimeric anti-human CD23 antibody wherein the light chain variable domain consists of the variable domain polypeptide encoded by SEQ ID NO: 1, the heavy chain variable domain consists of the variable domain polypeptide encoded by SEQ ID NO: 2, and the constant region is a human constant region selected from the group consisting of human gamma –1 and human gamma –3 constant regions. New claim 71 is directed to the chimeric anti-human CD23 antibody of claim 42, wherein the light chain variable domain consists of the polypeptide encoded by nucleotides 58-390 of SEQ ID NO: 1, and the heavy chain variable domain consists of the polypeptide encoded by nucleotides 58-423 of SEQ ID NO: 2. Support for amended claim 42 and new claim 71 is found in the specification on pages 44-45, which describe the light chain variable domain of antibody 6G5 as the polypeptide encoded by nucleotides 58-390 of SEQ ID NO: 1, and on pages 47-49, which describe the heavy chain variable domain of antibody 6G5 as the polypeptide encoded by nucleotides 58-423 of SEQ ID NO: 2.

Claims 48 and 49 are amended to be directed to a chimeric anti-human CD23 antibody wherein the light chain variable domain consists of the variable domain polypeptide encoded SEQ ID NO: 3, the heavy chain variable domain consists of the variable domain polypeptide encoded by SEQ ID NO: 4, and the constant region is a human constant region selected from the group consisting of a human gamma –1 constant region and a human gamma –3 constant region. New claims 72 and 73 are directed to the chimeric anti-human CD23 antibody of claims 44 and 49, respectively, wherein the light chain variable domain consists of the polypeptide encoded by nucleotides 67-387 of SEQ ID NO: 3, and the heavy chain variable domain consists of the polypeptide encoded by nucleotides 58-411 of SEQ ID NO: 4. Pages 51-52 of the specification describe the light chain variable domain of antibody 5E8 as the polypeptide encoded by nucleotides 67-387 of SEQ ID NO: 3, and pages 53-54 describe the heavy chain variable domain of antibody 5E8 as the polypeptide encoded by nucleotides 58-411 of SEQ ID NO: 4.

Amended claim 49 and new claim 73 further state the exception that the asparagine codon encoded by nucleotides 289-291 of SEQ ID NO: 4 is replaced with a lysine codon, as described, for example, on page 55, lines 20-30.

Patentability Remarks:

Claims 42, 48, and 49 and their dependent claims were rejected under 35 U.S.C. §112, first paragraph, for non-enablement and lack of written description of a chimeric anti-human CD23 antibody wherein the light and heavy chain variable domains comprise the polypeptides encoded by SEQ ID NOs: 1 and 2, respectively, or the polypeptides encoded by SEQ ID NOs: 3 and 4, respectively. The claims are amended to be directed to a chimeric anti-human CD23 antibody wherein the light and heavy chain variable domains consist of the variable domain polypeptides encoded by the disclosed nucleotide sequences. The specific nucleotide sequences in SEQ ID NOs:1-4 encoding the light and heavy chain variable domains are described in the specification on pages 44-45, 47-49, 51-52, and 53-54, respectively.

Claim 49 and its dependent claims were also rejected under 35 U.S.C. §112, first paragraph, for lack of written description (new matter) because the sequence listing shows glutamine, not asparagine, at codon 75 (see page 12 of the office action). The reference to codon 75 in claim 49 reflects the antibody codon numbering scheme shown on page 54 of the specification. To ensure that the mutated site identified in the claim is consistent with the sequence listing, claim 49 is amended to specify that the asparagine codon that is replaced with a lysine codon is encoded by nucleotides 289-291 of SEQ ID NO: 4, which is shown as codon 75 in the sequence on page 54 of the specification. The position of the mutated site in SEQ ID NO:4 can be verified by comparing the sequence of 5' primer M1653 in Table 5 on page 59, which was used to introduce the mutation, to the nucleotide sequence of SEQ ID NO:4.

The office action states that claims 61-69, directed to a pharmaceutical composition, are rejected under 35 U.S.C. §112, first paragraph, because the specification does not adequately teach how to use the claimed pharmaceutical composition for the treatment of *any* disease, so that undue experimentation would be required to use the claimed pharmaceutical composition. This ground of rejection is without merit. As discussed in the previous response, the application provides experimental data that demonstrates that the claimed composition acts as a drug *in vivo* to inhibit IgE production in experimental hu-SCID mice

that have human immune systems. As taught in the specification, many pathological conditions (e.g., asthma, allergic rhinitis, atopy) are mediated by IgE (see pages 75-78), and suppression of IgE synthesis in a patient with such a condition is generally regarded as a therapeutic strategy for treating the condition. Persons skilled in the art would therefore regard the disclosed experimental *in vivo* data as providing a reasonable expectation that administration of the claimed pharmaceutical composition to a person suffering from an IgE-mediated pathological condition such as those described in the specification would provide therapeutic benefit to the treated individual. The office action does not offer any scientific evidence or rationale that would cause one skilled in the art to doubt the therapeutic efficacy of the claimed pharmaceutical composition. The Applicants submit that the requirements of 35 U.S.C §112, 1st paragraph, are met by the present application with regard to claims drawn to a pharmaceutical composition.

The applicants respectfully submit that the original specification provides written description for the amended claims and enables persons skilled in the art to use the claimed invention successfully without undue experimentation. Withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

Conclusion

All rejections having been addressed, it is respectfully submitted that the present application is in condition for allowance and a Notice to that effect is earnestly solicited. If any points remain in issue, which the examiner feels may be best resolved through a personal or telephone interview, he is kindly requested to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,
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